UNITED STATES CENTRAL COMMAND
7115 SOUTH BOUNDARY BOULEVARD
MACDILL AIR FORCE BASE, FLORIDA 33621-5101

REPLY TO
ATTENTION
OF:

CCSG

15 November 2004

MEMORANDUM FOR See Distribution

SUBJECT: CENTCOM Policy on Cutaneous Leishmaniasis Diagnosis and Treatment

1. References.

a. Assistant Secretary of Defense (Health Affairs), Subject: Medical Advisory – Leishmaniasis, 12 September 2003.

b. Office of the Surgeon General of the Army Memorandum, Subject: Policy for Diagnosis and Treatment of *Leishmaniasis* sp. Diseases, 23 December 2002.

c. Office of the Surgeon General of the Army Memorandum, Subject: Guidance for the Management of Suspected Cutaneous Leshmaniasis in Operation Iraqi Freedom and Operation Enduring Freedom, 10 September 2004.

d. Office of the Surgeon General of the Army Policy Memo 04-003, Subject: Use of Tele-Dermatology Consults Prior to Patient Evacuation from Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) Locations, 20 May 2004.

e. Executive Summary, DASG-PPM-NC, 31 DEC 03, subject: Leishmaniasis among soldiers deployed to OIF/OEF.

f. FM 4-02.33, Control of Communicable Diseases Manual, 18th Edition, 2004.

2. Applicability. This policy is applicable to all CENTCOM components, CJTFs and elements deployed to the CENTCOM AOR.

3. Leishmaniasis is a preventable disease caused by *Leishmania* sp. parasites transmitted by the bite of infected sand flies.

a. Leishmaniasis is endemic throughout the CENTCOM AOR, including Iraq and Afghanistan. There are several forms of this disease (cutaneous, mucocutaneous, visceral, and viscerotrophic). The incubation period varies from one week to many months.

b. Diagnosis requires special techniques and culture media to isolate and properly identify the organism.

4. The key to preventing all forms of Leishmaniasis is enforcement of personal protective measures (properly wearing permethrin treated uniforms, properly using permethrin treated bed nets, and properly applying DEET repellant to exposed skin) and implementing effective vector control programs.

5. Cutaneous leishmaniasis (CL) is a disease characterized by one or more chronic, frequently ulcerative, skin lesions. While diagnosis can be difficult, CL should be suspected in any individual with a chronic ulcerative skin disorder with features that include; refractory to at least one week antibiotic treatment and lesions found predominantly in exposed skin areas lasting greater than 3 weeks in duration.

6. Visceral leishmaniasis (VL) is the internal form of the disease which is characterized by fever, weakness, wasting, an enlarged spleen, and a lowered blood count. If untreated, VL is generally fatal. VL should be considered in the differential diagnosis of any patient presenting with a persistent febrile illness. This is especially important if the patient has associated splenomegaly and/or pancytopenia and/or liver function test abnormalities.

7. All suspected cases of CL based on the criteria listed in paragraph 5 should be biopsied by the referring Health Care Provider (HCP) via standard techniques described in enclosure 1 or referred to in-theater facilities to have the procedure performed.

a. Instructional media on biopsy and scraping is available online at http://www.pdhealth.mil/ or http://www.afip.org/departments/infectious/lm/.

b. Non-US coalition personnel can also use these techniques or choose to use their normal diagnostic channels.

c. The methodology outlined will allow service members to remain with their unit until a positive diagnosis is determined.

d. For all suspected cases have the patient and the HCP conducting the biopsy complete the epidemiologic work sheet (enclosure 2). This form will be sent with the biopsy and slides to the diagnostic lab.

e. A copy of the work sheet will also be sent through appropriate channels to the CENTCOM Command Surgeon's office for epidemiologic tracking on SIPR at ccsg-pmo@centcom.smil.mil.

8. Typical CL treatment regimen is 20 days in duration. It is extremely important that personal protective measures identified in paragraph 4 are enforced during and after treatment. After completion of uncomplicated treatment, service members will return to their unit and are fully deployable. The following treatment guidance is provided.

a. Small (<2.5 cm) few in number (<4) Lesions not involving joints, face, ears or other cosmetically sensitive areas.

(1) No Treatment. Patients with old lesions demonstrating epithelialization (healing) should not be treated in general. Conversely, patients with more recent lesions that are actively ulcerated are better candidates for active treatment. A discussion of therapeutic options with the patient should always include the fact that CL is self-limited although the decision not to treat may prolong the duration of the ulcerations and/or result in more scarring.

(2) ThermoMed ™, a heat delivery system, is an option now available for the treatment of CL. Efficacy is reported to be quite good - although less than Pentostam. This treatment is given in a single application setting and delivers a controlled second degree burn. ThermoMed ™ application may produce bullous lesions in a significant number of cases and secondary superficial skin infections may occur if local wound infection control measures are not taken. Gentamicin or Bacitracin ointment and a non-stick, non-occlusive dressing should be used after ThermoMed ™ application. Scarring can result from this treatment although this is usually no greater than from CL itself. Dressing and ointment should be changed twice daily. This treatment modality will be available at medical treatment facilities as determined by the CJTF surgeon. Patients with non-healing and/or expanding lesions should be considered for this mode of treatment. Considerations that would not support the use of this device would be evidence of local dissemination. This may include daughter satellite lesions, regional adenopathy and palpable lymphatic chain nodules. Only providers trained and credentialed in usage of the device will be authorized to perform treatments. The patient's health care provider can perform follow-up for local wound checks.

b. Large (≥ 2.5 cm) and numerous (4 or more) lesions or lesions involving joints, face or other cosmetically sensitive areas.

(1) Pentostam has the highest efficacy and is used in more severe cases of CL. It can also be considered in any patient with non-healing CL.

(2) Pentostam is available only under a research protocol at limited treatment facilities. The typical treatment for CL requires either 10 or 20 days of therapy depending on the protocol used.

(3) Treatment with Pentostam will occur at treatment centers per service specific guidance.

c. Non-FDA approved in-theater treatments other than ThermoMed ™ may be considered by providers after discussing the risks and benefits of the treatment with their patients. Some of these are found in reference c.

9. The outcome of treatment may not be known for 60-90 days. It is extremely important that personal protective measures identified in paragraph 4 are enforced during this time period. The appearance of new lesions or enlargement of old lesions constitutes treatment failure. Healing of old lesions and absence of new lesions in the 60-90 days after treatment defines treatment

success. The considerations contained in this policy concerning the decision to provide active treatment in the first place are equally relevant to the decision to treat a second or third time.

10. Suspected cases of CL should not be evacuated out of theater for biopsy. Patient evacuation for treatment should only occur after a positive biopsy or scraping has established the diagnosis of CL. Based on the species and the extent of the disease there is some discretion allowed on the urgency of evacuation.

a. Patients scheduled to receive ThermoMed ^{TM} treatment will be evacuated as routine category to a designated theater treatment facility and returned to their referring unit after treatment.

b. Pentostam therapy will occur at treatment centers per service specific guidance. Evacuations for Pentostam therapy will be classified as routine category and coordinated through the Joint Patient Movement Requirements Center (JPMRC) per theater validation and prioritization requirements. Patients will be returned to duty after therapy.

11. If the diagnosis is confirmed for VL, the service member will be evacuated as a Priority. Initial testing may confirm the presence of *Leishmania*, but with a delay of several weeks for actual species identification (*L. major* versus *L. tropica*). The individual's evacuation should not be delayed pending species identification in cases where the lesion fit the criteria of paragraph 8.a.

12. Points of contact are MAJ Bill Darby, CENTCOM Force Health Protection Officer (darbywm@centcom.mil) and MAJ John Maza, CENTCOM Preventive Medicine Officer (mazajp@centcom.mil) or telephone 813-827-6397(DSN 651).

DOUGLAS J. ROBB
COL, USAF, MC, CFS
Command Surgeon

Enclosures
1. Leishmaniasis Lesion Evaluation and Biopsy Procedures
2. Leishmaniasis Patient Information Sheet

Distribution:
CDR, ARCENT
CDR, CENTAF
CDR, MARCENT
CDR, NAVCENT
CDR, SOCCENT
CDR, MNF-I
CDR, CFC-A
CDR, CJTF-HOA

Leishmaniasis Lesion Evaluation and Biopsy Procedures

1) Evaluation of lesion:

- Consider Leishmaniasis for any non-healing lesion present for more than 3 weeks.

- Complete appropriate documentation paperwork.

- Initiate antibiotic therapy with Augmentin 875 mg twice a day for 10 days. For persons allergic to Augmentin or penicillin, use Levaquin (levoflaxocin) 500 mg once a day for 7 days.

- Document size and appearance of lesion by photograph or diagram.

- Evaluate lesion after 10 days of antibiotics. Ideally, the lesion should be evaluated by the same health care provider.

- Biopsy and scrape any lesion that is persistent or worsening.

2) Biopsy procedure:

- Self-contained diagnostic kits are available upon request from the Walter Reed Institute of Research(WRAIR) [Commercial Phone: (301) 319-9956/DSN 312-285-9956]. This kit enables proper collection of diagnostic material and to be mailed to WRAIR for histological and microbiological study for the Leishmania parasite.

- Photos of the lesion prior to the scraping and biopsy being done should be accomplished if the practitioner has the capability. E-mail these photos and clinical history to derm.consult@us.army.mil and WRAIR through LTC Peter Weina at peter.weina@na.amedd.army.mil. Additionally, submit the digital photos to the Armed Forces Institute of Pathology (AFIP) telemedicine server at https://www3.afip.org to ensure that they are incorporated into the registry.

- An area of the lesion needs to be cleaned thoroughly with alcohol pads (at a minimum) and dried.

- The anticipated area of biopsy should be anesthetized with 1% lidocaine by infiltration.

- A 4 mm sterile disposable punch or sterile scalpel (#15, #11, or #10) should be used to remove a piece of tissue approximately 3 to 4 mm in circumference and approximately 1 mm deep from the edge of the lesion (see photo for preferred area of biopsy). Lesions on the face, anterior of the neck, and near larger vessels and/or nerves need to be biopsied with extreme caution and a simple surface scraping may be preferred to a true biopsy (scrape lightly to elicit an exudate but not vigorously enough to cause bleeding).

- The biopsy should be placed on a sterile, clean, dry gauze 2X2 briefly to absorb excess blood on the tissue that may interfere with the reading of the touch preparations.

- The tissue should be grasped with forceps and impression smears made on clean slides (4 for each biopsy) by rubbing the tissue gently across the surface of the slide in a circular

motion. If a scraping is done, the material removed with the scraping should be placed in the alcohol and the slides should be pressed onto the lesion itself for the impression smear.

- Dry thoroughly. Fix with methanol if available.

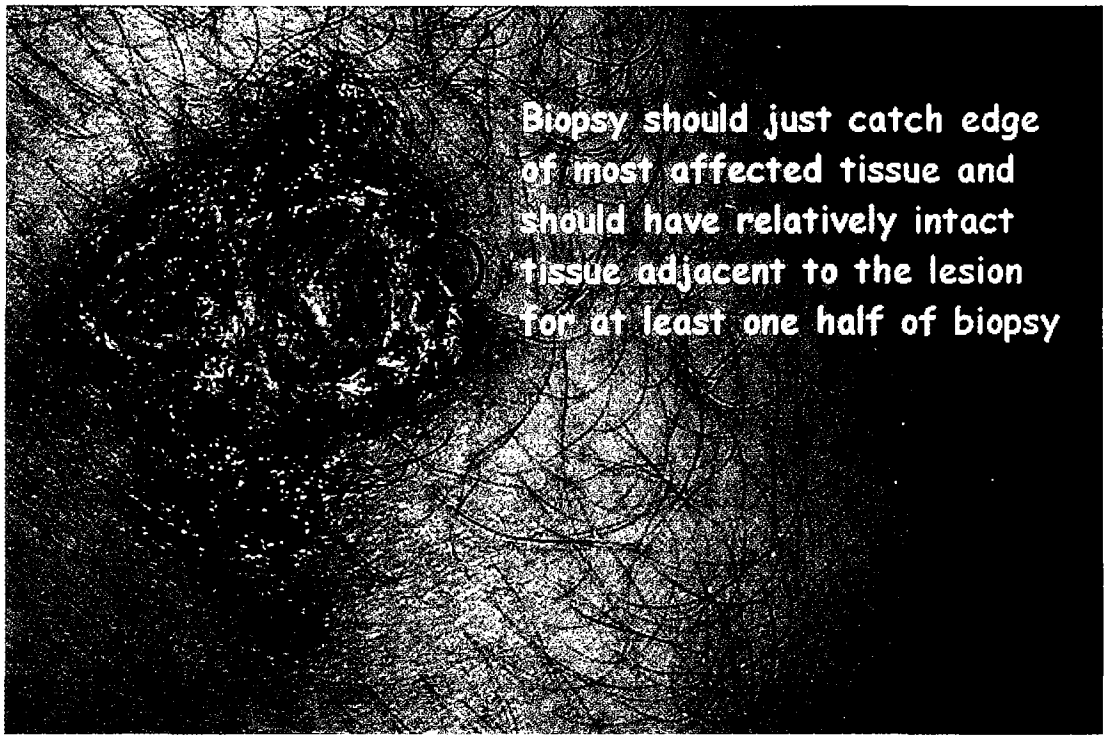
- The tissue biopsy (after the impression smears are made) or scraped material should then be placed in a very small amount of ethyl alcohol (just enough to cover the specimen) in a leak proof vial (such as a "nunc" transport tube).

- Complete the patient information sheet and include with the specimen for each patient biopsied.

- After evaluation by the Theatre Pathologist, the specimens will be shipped via DHL or Federal Express to the address below. The container should be labeled as diagnostic specimens and no shipping permit is required. POC LTC Peter Weina, peter.weina@na.amedd.army.mil (DSN: 312.285.9956/Comm: 301.319.9956).

Director, Leishmania Diagnostic Laboratory
ATTN: LTC Peter Weina
Division of Experimental Therapeutics
503 Robert Grant Avenue
Walter Reed Army Institute of Research
Silver Spring, Maryland 20910-7500

Preferred biopsy area:



Leishmaniasis Lesion Evaluation and Biopsy Procedures

3) Scraping Procedures (photos below).

- Anesthetize the lesion with lidocaine.

- Rub off the overlying dry scab with an alcohol gauze pad. The lesion should have tissue exposed.

- Firmly press a scalpel blade against the ulcer bed and scrape across the ulcer bed.

- The resulting tissue pulp is smeared on a slide and allowed to air dry.

- Perform a rapid Giemsa stain.

- After evaluation by the theater pathologist, all scraping smears (whether read locally as positive or negative), along with the corresponding PCR tube, should be submitted to the Department of Infectious and Parasitic Disease Pathology at AFIP for quality control, confirmation, and inclusion in the AFIP Leishmaniasis Registry. If AFIP confirms a negative smear, the PCR tube will be sent to WRAIR for PCR analysis.

Armed Forces Institute of Pathology
ATTN: Receiving and Accessions Division (AFIP-RRS)
Room G-071, Building #54
6825 16th Street, N.W.
Washington, DC 20306-6000

Leishmaniasis Patient Information Sheet

Service member completes Part A; Clinical provider completes Part B

PART A – SERVICE MEMBER

Today's Date: _____

Patient Name: _____ SSN: _____ Rank/ Service: _____

Race: _____ Blood type: _____ Weight (lbs): _____ DOB: _____

Med Allergies: Y/N Allergic to: _____

Unit: _____ Date arrived in Theater: _____

Places/dates lived in Theater: (use separate sheet if necessary)
Country: _____ Base/Camp: _____ Dates: _____
Country: _____ Base/Camp: _____ Dates: _____
Country: _____ Base/Camp: _____ Dates: _____

Were rodents present around bivouac area? Y / N Were dogs in the area? Y / N

Places You Slept	# Weeks or N/A	Screens Or Windows? (Y/N)	A/C (Y/N)	Use Bednet (Always/ Sometimes/Never)	Use Repellent (Always/ Sometimes/Never)	Insect Bites Per Night? *(<5, 5-20, >20)*
Vehicle or Ground						
Tent						
Building						

Your Use of Personal Protective Measures (PPM)	Product Was Not Available to Service Member	Product was Available to Service Member			
		Did Not Use	Used Only After Insect Bites – <u>After how many bites?</u> *(<5, 5-20, >20)*	Used Every Night	Used Other Times *Describe When*
Bed Net, Treated w/ Permethrin					
Bed Net w/o Permethrin					
Permethrin Treated DCUs					
DEET (green tube) on Skin					
Commercial Insect Repellent *If Yes, Specify in Box*					

PART B – CLINICAL PROVIDER (*Send form with slides and biopsy*)

Lesion Location & #: _____ Duration? _____

Antibiotic Treatment (type/dose/length): _____

Photos Taken? **N / Y** If Yes, sent to AFIP, WRAIR and TeleDermatology **N / Y**. Providers are encouraged to utilize <u>derm.consult@us.army.mil</u> for all challenging skin rashes or growths by simply e-mailing pertinent history with attached digital images to this address.

Procedures Done: Scrape Biopsy: **N / Y** Punch Biopsy: **N / Y** Touch Prep: **N / Y**
Culture: **N / Y** Preserved Tissue: **N / Y** PCR: **N / Y**

Date Eval: _____ MTF: _____ POC: _____ Phone: _____
E-mail(POC): _____ E-mail (Provider): _____
Clinician Name (stamp)

_____

Pathology Results: (POS / NEG)
Pathologist Notes:

_____